

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Rivaroxaban Versus Warfarin in Patients With Left Ventricular Thrombus After Acute Myocardial Infarction: A Randomized Controlled Pilot Trial

#### Protocol summary

##### Study aim

Comparison of the safety of rivaroxaban-based versus warfarin-based antithrombotic regimens in patients with acute ST elevation myocardial infarction left ventricular thrombosis

##### Design

Two parallel groups randomized trial with blinded outcome assessment

##### Settings and conduct

The trial will take place in hospital setting (Rajaie cardiovascular medical and research center along with Tehran heart center) on patients with acute STEMI complicated by LVT. Patients will be randomized via central web based method into two interventional groups with two different antithrombotic regimen. Treating physician and patients will not be blinded. Thrombus status (assessed via echocardiography) and bleeding complications will be evaluated after 1 and 3 months.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. All patients with the age of 18-80 admitted with an acute STEMI 2. Presence of left ventricular thrombosis, confirmed by transthoracic echocardiography 3. Signed informed consent Exclusion criteria: 1. Previous history of mechanical prosthetic heart valve 2. Candidate for coronary artery bypass graft surgery 3. Active bleeding 4. Cardiogenic shock 5. Acute kidney injury or chronic kidney disease with a GFR<30 ml/min 6. Liver failure(Child-Pugh class C) 7. Sensitivity or intolerance with rivaroxaban/warfarin

##### Intervention groups

The study contains two groups: - Intervention: rivaroxaban (15 mg daily, oral) plus clopidogrel (75 mg daily, oral) plus ASA (80 mg daily, oral; only during the first 7 days) - Control: warfarin (target INR of 2.0-3.0) plus clopidogrel(75 mg daily, oral) plus ASA (80 mg daily, oral; only during the first 7 days)

##### Main outcome variables

LVT resolution; LVT size; thromboembolic events; all-cause death; bleeding

#### General information

##### Reason for update

There were few cases limited to acute STEMI who have undergone PCI. Consequently we have expanded our inclusion criteria to all patients complicating with acute STEMI

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181022041406N4**  
Registration date: **2020-07-30, 1399/05/09**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-08-09, 1400/05/18**

Update count: **1**

##### Registration date

2020-07-30, 1399/05/09

##### Registrant information

##### Name

Parham Sadeghipour

##### Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2392 2092

##### Email address

psadeghipour@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2022-06-22, 1401/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Rivaroxaban Versus Warfarin in Patients With Left Ventricular Thrombus After Acute Myocardial Infarction: A Randomized Controlled Pilot Trial

**Public title**  
Rivaroxaban in Left Ventricular Thrombus

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
All patients with the age of 18-80 admitted with an acute STEMI Presence of LV thrombosis, which were confirmed by transthoracic echocardiography Signed informed consent

**Exclusion criteria:**  
Previous history of mechanical prosthetic heart valve  
Candidate for coronary artery bypass graft surgery  
Active bleeding Cardiogenic shock Acute Kidney Injury or Chronic Kidney Disease with a glomerular filtration rate <30 ml/min Liver failure (Child-Pugh class C) Sensitivity or intolerance to rivaroxaban/warfarin/P2Y12 inhibitors

**Age**  
From **18 years** old to **80 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization will be performed via permuted block randomization method. Allocation will be generated via a web based system and consequently concealment will be central using computer software. Unit of randomization will be individual patients and no stratification will be applied.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Blinding will be performed only for the adjudicator level and analyzer level, and patients and physicians won't be blind in this study

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

**Name of ethics committee**

Tehran Heart Center

**Street address**

Tehran Heart Center, Jalal-e-Al-e-Ahmad Hwy, Northern Kargar Ave, Tehran province, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1416753955

**Approval date**

2020-06-08, 1399/03/19

**Ethics committee reference number**

IR.TUMS.THC.REC.1399.004

## Health conditions studied

1

### Description of health condition studied

Pre-acute ST-segment Elevation Myocardial Infarction (STEMI) Left Ventricular (LV) thrombosis

**ICD-10 code**

I23.6

**ICD-10 code description**

Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction

## Primary outcomes

1

### Description

Resolution of left ventricular thrombus

**Timepoint**

3 months after initiation of antithrombotic therapeutic regimen

**Method of measurement**

Transthoracic echocardiography

## Secondary outcomes

1

### Description

Bleeding after initiation of antithrombotic regimen

**Timepoint**

1 month and 3 months after initiation of antithrombotic regimen

**Method of measurement**

ISTH criteria

## Intervention groups

1

### Description

Intervention group: Rivaroxaban-based antithrombotic therapeutic regimen

### Category

Treatment - Drugs

2

### Description

Control group: Warfarin-based antithrombotic therapeutic regimen

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Rajaie cardiovascular medical and research center

#### Full name of responsible person

Parham Sadeghipour

#### Street address

Vali-Asr ave, Hashemi Rafsanjani Exp

#### City

Tehran

#### Province

Tehran

#### Postal code

1995614331

#### Phone

+98 21 2392 2092

#### Email

psadeghipour@rhc.ac.ir

2

### Recruitment center

#### Name of recruitment center

Tehran Heart Center

#### Full name of responsible person

Yaser Jenab

#### Street address

North Kargar Ave

#### City

Tehran

#### Province

Tehran

#### Postal code

1313814117

#### Phone

+98 21 8802 9600

#### Email

yasjenab@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Rajaie cardiovascular medical and research center

#### Full name of responsible person

Feridoun noohi

#### Street address

Vali-Asr Ave, Hashemi Rafsanjani Exp

#### City

Tehran

#### Province

Tehran

#### Postal code

1995614331

#### Phone

+98 21 2392 2020

#### Email

fnoohi@yahoo.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Rajaie cardiovascular medical and research center

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

#### Full name of responsible person

Parham Sadeghipour

#### Position

Associated Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Cardiology

#### Street address

Vali-Asr Ave, Hashemi Rafsanjani Exp

#### City

Tehran

#### Province

Tehran

#### Postal code

1995614331

#### Phone

+98 21 2392 2092

**Fax**

**Email**

psadeghipour@hotmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Rajaie cardiovascular medical and research center

**Full name of responsible person**

Parham Sadeghipour

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Vali-Asr Ave, Hashemi Rafsanjani Exp

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 2392 2092

**Email**

psadeghipour@hotmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Rajaie cardiovascular medical and research center

**Full name of responsible person**

Parham Sadeghipour

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Vali-Asr Ave, Hashemi Rafsanjani Exp

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 2392 2092

**Email**

psadeghipour@hotmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available